Remarks

Claims 37-85 are pending in the subject application. Favorable consideration of the claims, in view of the remarks set forth herein, is earnestly solicited.

The current invention provides an efficient and effective method for providing ventilation to a patient wherein data representing the body length of a patient is input into a ventilator control device that calculates ventilation parameters, ventilatory limits, or ventilation alarm settings based on the input body length, and wherein proper ventilation is provided in accordance with the calculated ventilation figures. The method is particularly advantageous because it is very simple and accurate. As discussed below, the prior art contains no teaching or suggestion of the applicants' unexpectedly advantageous method.

Claims 37-85 have been rejected under 35 U.S.C. §103(a) as obvious over Kanesaka (U.S. Patent No. 5,042,470) in view of Heinonen (U.S. Patent No. 5,649,531) and Haluszka *et al.* ("Whole Body Plethysmography"). The applicants respectfully traverse this grounds of rejection because the cited references, alone or in combination, do not teach or suggest the methods claimed by the current applicants.

Independent claims 37, 48, and 66 recite a method for operating a ventilator in which data representing only the body length of the patient to be ventilated is entered into the ventilator via an input device. That is, the user inputs a distance measurement into the ventilator, e.g., in inches, feet and inches, or centimeters, representing the height of the patient. Inputting this length measurement can be done using a key pad, numerical dial or any other input device that is capable of setting this distance.

Once the patient's body length data is entered, claim 37 indicates that the ventilator calculates a ventilation parameter based on this data and an action is taken based on the ventilation parameter. In claim 37, the ventilating function of the ventilator is controlled based on the ventilation parameter. In claim 48, the operating limits of the ventilator, i.e., the ventilatory limits, are set based on the length data. In claim 66, a ventilation alarm is set based on the length data. As discussed in detail below, the cited references, taken alone or in combination, do not teach or suggest these features of the present invention.

The '470 Patent

The Examiner cites U.S. Patent No. 5,042,470 to Kanesaka ("the '470 patent") for the proposition that it was known to input data representing only height into the ventilator. To this end, at page 2-3 of the Office Action it is stated:

> In regards to claims 37-85, Kanesaka substantially discloses the instant applications' claimed invention to include the provision of a ventilator system...that contains a control device (Col. 4, lines 15-32, ...), with a means for inputting data (note col. 4, lines 17-20) that provides ventilation to a patient and that calculates ventilator parameters utilizing such data which includes data that only represents height..., but does not explicitly disclose that the data is input in the raw form and that the control device renders the calculation of such data into the necessary ventilatory parameter.

The applicants respectfully submit that this statement appears to be internally inconsistent. On the one hand, the Examiner appears to indicate that the '470 patent teaches that height alone can be a factor that is used by the ventilator to set the operating parameter of the ventilator automatically. On the other hand, the Examiner admits that the '470 patent does not explicitly teach inputting height data in its raw form and using the data to calculate the necessary ventilatory parameters.

While the applicants agree with the Examiner's second conclusion, they respectfully disagree with the first. The '470 patent does not teach or suggest that height alone can be used to set the operating parameter of the ventilator automatically. Column 4, lines 16-24, of the '470 patent states:

> When the ventilating system of the present invention is activated, the main section (1) and the auxiliary section (5) must be *manually set*. Namely, based on a patient weight, height, sex, and other clinical conditions, ventilator pressure, tidal volume, I/E (Inspire/Expire) ratio, frequency of breath, and etc. are set at the main section (1) and the auxiliary section (5). (emphasis added)

This passage from the '470 patent teaches that the ventilator settings, i.e., the operating parameters of the ventilator, are set manually by the respiratory therapist based on the physical condition of the patient to be ventilated. This passage merely describes a conventional technique for setting up a ventilator. That is, the respiratory therapist observes the patient to assess his or her anatomical factors, such as weight, sex, and height, and to determine the patient's clinical factors,

such as whether the patient has suffered a trauma or suffers from a respiratory disorder, for example, COPD. Based on these assessments, the respiratory therapist sets the operating parameters of the ventilator, such as the tidal volume to be delivered during each respiratory cycle and the respiratory rate.

Nothing from the '470 patent teaches or suggests that the ventilator perform any calculation or other operation to set up the ventilator automatically based on the patient's height. Quite the contrary, the '470 patent explicitly teaches that setting up the ventilator is done *manually* - using conventional techniques based on the physical properties of the patient. To suggest that the ventilator is automatically setting an operating parameter based on the input data, is to misread column 4 of the '470 patent or, perhaps, to read too much into that description.

The '531 Patent

Acknowledging that the '470 patent does not teach inputting height data in its raw form and using that data to calculate the necessary ventilatory parameters, the Office Action further cites U.S. Patent No. 5,649,531 to Heinonen ("the '531 patent") for the proposition that it was well known to input raw data into a ventilator and control the operation of the ventilator based on such data.

The '531 patent teaches that the operation of an anesthesia administering system can be controlled so that the proper concentration of anesthesia is delivered to the patient. However, the '531 patent does not teach or suggest setting the operating parameters of the ventilator based on the patient's height.

The Examiner appears to be relying on the '531 patent only for the proposition that it would have been obvious to automate the parameter setting operations required by the ventilator of the '470 patent. The applicants respectfully do not agree that one skilled in the art would understand how this can be done based on the teachings of the '531 patent.

The '531 patent teaches that flow meters **15, 16, 29, 33,** and **39,** and temperature sensor **40** are monitored to control the flow of gas and anesthesia to the patient in a feedback fashion. This patent says nothing about how (or whether) the patient's weight, sex, or height could be used to set the operating parameters of the ventilator. The mere fact that flow to the patient can be

automatically controlled in a feedback fashion, does not suggest the further leap that setting the basic operating parameters of the ventilator, such as the tidal volume and respiratory rate, can be automated.

The Haluszka Reference

Finally, the Examiner cites the Haluszka reference for the proposition that the patient's height can be the sole criteria that is used to set up the ventilator. The Examiner relies on the statement in the Haluszka reference that reads, "[it] was stated, that body height was the best predictive variable for all measured parameters." According to the Office Action, this passage suggests to one of ordinary skill in the art that a patient's height can be entered into the ventilator and that the ventilator would automatically determine the tidal volume and respiratory rate, for example, set from this data. The applicants must respectfully disagree.

Assessing the condition of the lungs is typically done via spirometry, in which the patient performs a series of respiratory maneuvers during which the patient's flow/volume is measured with a spirometer. The results of the spirometer are various lung volumes and capacities. For example, spirometry yields a measure of a patient's vital capacity (VC), functional vital capacity (FVC)(also referred to a functional residual volume (FRV)), and FEV_1 which the forced expiratory volume during one minute.

These spirometry-measured volumes and capacities are well known and understood parameters used in the respiratory arts to measure the function of a patient's lung. These are not parameters that are used to provide ventilation to a patient via a ventilator, i.e., they are not used to set up a ventilator (see claim 37). Spirometry-measured parameters are also not used to set ventilatory limits or alarm thresholds for a ventilator (see claims 48 and 66).

In the Haluszka reference, the author analyzes whether whole body plethysmography, which means measuring the overall size of the patient's body, is useful in diagnosing the condition of a patient's lungs. In essence, the Haluszka reference attempts to determine whether some anatomical feature of the body provides the same or similar data as that obtained during spirometry. The conclusion of the Haluszka reference is that out of all of the physical features of the patient that were

compared, the patient's height provides the best correlation with the spirometry measured volumes and capacities, at least in children. That is, for a normal, healthy child of a particular height, he or she should have a given VC, FVC, and FEV_1.

It can thus be appreciated that the Haluszka reference teaches a surrogate to spirometry, in which vital volumes and capacities normally measured via spirometry can be replaced with a height measurement, at least in children. While such spirometry-measured vital capacities may be of interest in assessing lung function, they are not used by a technician in setting up a ventilator, i.e., in determining the ventilation parameters that serve as the basis for providing ventilation to a patient. Therefore, there is no basis to conclude that a height measurement, which, according to the Haluszka reference, predicts a volume or lung capacity corresponding to that measured via spirometry, could be applied to set up a ventilator for delivering ventilation to a patient.

Spirometry-measured volumes and capacities (VC, FVC, FEV_1), especially those predicted based on height via the Haluszka reference, do not serve to predict how a ventilator should be configured to deliver ventilation to a patient. For example, a ventilator typically must be set to deliver a certain tidal volume at a certain respiratory rate. Those skilled in the art understand that spirometry-measured volumes and capacities (VC, FVC, FEV_1) measured indirectly based on height (such as taught by the Haluska reference), do not correlate to a tidal volume or a respiratory rate. Therefore, those skilled in the art would not consider it obvious to measure the height of the patient as an input to a ventilator, because the volume or capacity measurement predicted based on height does not provide the correct volume, namely tidal volume V_T, needed to set up a ventilator. In addition, the volume or capacity measurement predicted based on height does not provide any suggestion as to what respiratory rate to deliver to the patient.

It must also be noted that the vital capacities measured based on height do not provide a reliable prediction of tidal volume if any (claim 38), and do not provide any prediction for what respiratory rate (claim 39), inspiratory flow rate (claim 40), I/E ratio (claim 41), inspiratory time (claim 42), minute ventilation (claim 43) or combinations thereof (see claims 44-47) is to be delivered to a patient during ventilation. Thus, dependent claims 38-44 are further distinguishable

over the cited references. Similar distinctions exist as to the claims depending from independent claims 48 and 66.

The Haluszka reference does not enable one skilled in the art to practice the presently claimed invention because it does not explain how the ventilator would set the tidal volume or the respiratory rate from the input height data. There is no enabling teaching that explains or even suggests that height alone can be used to by a control system in the ventilator because the Haluszka reference is not directed to treating a patient with a ventilator.

In addition, the correlation between the height of a child and a lung volume or vital capacity taught by the Haluszka reference is only very general. This lack of a specific or more definite correlation could lead one skilled in the art to conclude that the height measurement does not provide a better estimation of a ventilation parameter than merely observing the overall size of the patient and estimating the ventilation parameters from that observed size. Thus, the applicant respectfully submits that the Office Action is reading too much into the teachings of the Haluszka reference in concluding that one skilled in the art would be motivated to apply a height-based measurement to a ventilator.

Meaning of "Ventilation Parameter"

In the Office Action, the Examiner points out that the phrase "ventilation parameter" used in the claims is being given its broadest reasonable interpretation. As such, the Examiner concludes that the spirometry-type of measured volumes and capacities (VC, FVC, FEV_1) that are predicted based on height as taught by the Haluszka reference, are considered "ventilation parameters." The applicants must again respectfully disagree.

The phrase "ventilation parameter" used in claim 37, means a parameter that is used by a ventilator to provide ventilation to a patient. In this regard please note that lines 9-10 of claim 37 state that ventilation is provided in accordance with the ventilation parameter. That is, the meaning of the phrase "ventilation parameter", as used in claim 37, is limited to a parameter that is used by a ventilator in order to deliver ventilation to a patient. It is believed that by defining a specific use for the "ventilation parameter" in claim 37, the phrase "ventilation parameter" cannot be broadly

interpreted to include every parameter associated with respiration, such as spirometry-type of measured volumes and capacities (VC, FVC, FEV_1), because those skilled in the art understand that these "parameters" are not used to control ventilation delivered to a patient via a ventilator.

Combination of References

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine the teachings of the cited references to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The current invention advantageously simplifies the process for providing accurate ventilation to a patient by making it possible to identify and implement ventilation parameters based only on body length.

As noted above and as acknowledged in the outstanding Office Action, the '470 patent does not teach the applicants' unique method of providing ventilation based solely on body length. The '470 patent merely teaches a ventilation device that must be manually set to provide appropriate breathing gas (see, for example, col. 4, lines 17-24). The '470 patent teaches that the ventilation settings, which are manually established by the user, are based on "patient weight, height, gender, *and* other clinical conditions" (emphasis added, see col. 4, lines 17-24). There is no suggestion in the '470 patent that ventilation can be automatically provided to the patient based solely upon patient length. The applicants respectfully submit that manually establishing settings for a ventilation device using patient clinical conditions, as described in the '470 patent, in no way suggests the automated, accurate method of providing ventilation based solely on body length data. There is no reason to think that one skilled in the art would be motivated to modify the method described in the '470 patent to automate ventilation settings based upon patient length. In fact, the emphases on manually setting the ventilation device based on a combination of patient conditions essentially teaches away from the method of the current invention.

The '531 patent also fails to disclose establishing ventilation settings based solely on patient length to provide proper breathing gas to a patient. Thus, the skilled artisan would not have found in Heinonen any remedy to the defects previously noted in the '470 patent.

As discussed above, the Haluszka *et al.* reference does not teach, either expressly or impliedly, operating a ventilator to assist a patient in respirating. Moreover, Haluszka *et al.* fail to disclose a ventilator wherein the ventilation settings are automatically established based only on patient length to provide proper breathing gas to a patient. Thus, the Haluszka *et al.* reference fails to remedy, or even address, the defects previously noted in the '470 and '531 patents.

Thus, there is no suggestion or motivation in the prior art that would lead a person skilled in the art to arrive at the particular combination of steps which makes the subject invention particularly advantageous. As a matter of law, a finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicants' disclosure that provides such a teaching, and the applicants' disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

Combining prior art references without evidence of a suggestion, teaching, or motivation simply takes the inventors' disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). Additionally, the Court of Customs and Patent Appeals has stated, "[i]n determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." In re Linter, 458 F.2d 1013, 1016 (CCPA 1972).

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The mere fact that the purported prior art could have been modified or applied in a manner to yield applicants' invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection. "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.*

The references cited in the present Office Action do not provide any motivation to modify the cited teachings without the guidance of the applicants' disclosure. Without such a motivation, no *prima facie* case of obviousness has been made. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection set forth under 35 U.S.C. §103.

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

David Saliwanchik

David R. Saliwanchik
Patent Attorney
Registration No. 31,794
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

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